

08-7-00

A

Attorney's Docket No. 00-0050  
Client's Docket No.

**PATENT Utility APPLICATION COVER SHEET**

BOX PATENT APPLICATION  
HONORABLE ASSISTANT COMMISSIONER FOR PATENTS  
Washington, D. C. 20231

Sir:

Transmitted herewith for filing is the utility patent application of:

INVENTOR: WILSON T ASFORA

FOR: SUBDURAL EVACUATING PORT SYSTEM

**Enclosed are:**

- ☒ Postcard for receipt stamp and return.
- ☒ Applicant's Check for **\$453.00**, covering fees calculated below.
- ☒ Specification with Claims, Abstract, & Declaration & Power of Attorney
- ☒ A verified statement to establish small entity status under 37C.F.R § 1.9 and 37 C.F.R. § 1.27.
- ☒ 4 sheets of drawing.
- ☐ Cover Sheet & Assignment to: \_\_\_\_\_
- ☒ Information Disclosure Statement.

**The filing fee has been calculated as shown below:**

	(Col. 1) No. Filed	(Col. 2) No. Extra	SMALL ENTITY RATE	FEE
FOR: BASIC FEE			\$345	<b>\$345</b>
TOTAL CLAIMS <b>32</b>	-20=	<b>12</b>	x09	<b>\$108</b>
INDEPENDENT CLAIMS <b>3</b>	- 3=	<b>0</b>	x39	<b>0</b>
MULTIPLE DEPENDENT CLAIMS PRESENTED			+125	
<b>TOTAL</b>				<b>\$453</b>

DEPOSIT ACCOUNT AUTHORIZATION

The Commissioner is hereby authorized to charge any fees, which are not otherwise submitted and which may be required under 37 CFR 1.17 during the entire pendency of this application, to the Deposit Account # **11-0020**.

August 4, 2000

IVAR M. KAARDAL, Reg. No. 29,812  
KAARDAL & ASSOCIATES, PC  
3500 South First Ave. Circle-Suite 250  
SIOUX FALLS, SD 57105-5802  
(605) 336-9446 FAX (605) 336-1931  
e-mail: patent@kaardal.com

Date

08/04/00 09:33:23 080400

JC821 U.S. PTO  
08/04/00

JC542 U.S. PTO  
09/633573  
08/04/00

Applicant or Patentee: **WILSON T. ASFORA**

Serial or Patent Number:

Filed or Issued:

For: **SUBDURAL EVACUATING PORT SYSTEM**

**VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY  
STATUS (37 CFR 1.9(f) and 1.27(b) - INDEPENDENT INVENTOR**

As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees under section 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled as above and described in:

☒ the specification filed herewith.

☐ application serial number \_\_\_\_\_, filed \_\_\_\_\_.

☐ patent no. \_\_\_\_\_, issued \_\_\_\_\_.

I have not assigned, granted, conveyed or licensed and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

☒ no such person, concern, or organization

☐ persons, concerns or organizations listed below\*

\*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

FULL NAME: NOT APPLICABLE

☐ INDIVIDUAL

ADDRESS: NOT APPLICABLE

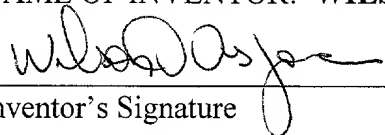
☐ SMALL BUSINESS CONCERN

☐ NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate (37 CFR 1.28(b)).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF INVENTOR: **WILSON T. ASFORA**

  
Inventor's Signature

Date: 8-1-00

004030" e f g e s i o

**In the United States Patent and Trademark Office**

In re Application of:  
WILSON T ASFORA


Filed: **UTILITY PATENT APPLICATION**

For: **SUBDURAL EVACUATING PORT SYSTEM**

Assistant Commissioner for Patents and Trademarks  
Washington, D.C. 20231

Date of Deposit: August 4, 2000

I hereby certify that the attached U.S. Patent Application, informal drawings, transmittal letter, priority document, and/or Preliminary Amendment are being deposited with the United States Postal Service under Express Mail service **#EL 493062831 US** on the date indicated above and is addressed to the Box Patent Application, Assistant Commissioner for Patents, Washington, D.C. 20231.



August 4, 2000  
Date

RANDI VANDER WILT  
KAARDAL & ASSOCIATES, PC  
3500 South First Ave. Circle-Suite 250  
SIOUX FALLS, SD 57105-5802  
(605) 336-9446 FAX (605) 336-1931  
e-mail patent@kaardal.com

Attorney's Docket No. K&A 00-0050

**APPLICATION**

**FOR UNITED STATES LETTERS PATENT**

----

**SPECIFICATION**

TO ALL WHOM IT MAY CONCERN:

BE IT KNOWN THAT I, **WILSON T. ASFORA**, a citizen of UNITED STATES, have invented a new and useful **SUBDURAL EVACUATING PORT SYSTEM** of which the following is a specification:

## **SUBDURAL EVACUATING PORT SYSTEM**

### **5 CROSS REFERENCE TO RELATED APPLICATION**

This application is a continuation-in-part of Application No. 29/105,951, filed June 4, 1999.

### **BACKGROUND OF THE INVENTION**

#### **10 Field of the Invention**

The present invention relates to systems for removing fluids from the subdural region of a patient and more particularly pertains to a new subdural evacuating port system for removing subdural fluid accumulations in a manner that is minimally invasive and promotes decompression, expansion, and recovery of the brain.

#### **Description of the Prior Art**

20 The subdural space of the human head is the space located between the brain and the lining of the brain, which is referred to as the dura mater (hereinafter referred to as the "dura"). Hemorrhages on the surface of the brain, for example, may cause a condition known as a subdural hematoma. The subdural hemorrhages may have a number of causes. For example, elderly persons may be more susceptible to subdural hemorrhages because as the brain ages it tends to become atrophic and the subdural space between the brain and the dura gradually enlarges. Bridging veins

between brain and dura frequently stretch and rupture as a consequence of relatively minor head injuries, thus giving rise to a collection of blood in the subdural space. Further, severe linear deceleration of the brain can result in the brain moving excessively with respect to the dura, often causing rupture of the bridging veins or the blood vessels on the surface of the brain, which can in turn cause subdural hemorrhages in the "normal", young, and otherwise healthy brain.

These subdural blood collections can be classified as acute subdural hematomas, subacute subdural hematomas, and chronic subdural hematomas. Acute subdural hematomas, which are associated with major cerebral trauma, generally consist primarily of fresh blood. Subacute subdural hematomas are generally associated with less severe injuries than those underlying the acute subdural hematomas. Chronic subdural hematomas are generally associated with even less severe, or relatively minor, injuries. The chronic subdural hematomas tend to be less dense liquid consisting of very diluted blood.

Another condition involving a subdural collection of fluid is a hygroma, which is a collection of cerebrospinal fluid (sometimes mixed with blood) beneath the dura, usually in an encapsulation or cyst.

One form of treatment for acute subdural hematomas is the performance of a craniotomy operation. This operation entails the removal (with eventual replacement) of a large portion of the skull, opening of the dura, and evacuation of the collection of blood. The craniotomy frequently necessitates the placement of a subdural drain, which comprises a tube extending through the hole created by

the craniotomy and into the subdural space for removing any additional accumulation of blood or fluid. The craniotomy is a highly invasive procedure that generally involves significant risk to the patient and an extended recovery period.

5

Since the subacute and chronic types of subdural hematomas primarily comprise collections of liquid, the treatment may range from the performance of a craniotomy to the use of a burr hole.

The burr hole operation generally comprises boring in the skull a  
10 hole that is smaller than the portion of skull removed in a craniotomy. The burr hole generally has a diameter of about 14 to 18 mm. Through the burr hole, extensive washing of the subdural space may be carried out. Frequently, a drain needs to be left in place through the burr hole, with the end of the drain being in  
15 communication with the surface of the brain in order to allow for postoperative drainage of any further accumulations of fluid. Again, the patient is exposed to a fairly invasive procedure and a relatively long recovery period.

20

The aforementioned drains are typically used in combination with the application of negative pressure through the tube of the drain. The typical level of the negative pressure applied by the drains frequently causes further hemorrhage of the brain, especially if the end of the tube should come in contact with the surface of the  
25 brain. Further, recurrence of subdural hematomas and hygromas is quite common in chronic cases as the brain generally fails to expand to fill the enlarged subdural space created by the collection of fluid. If the subdural space remains enlarged after removal of the fluid, additional fluid tends to collect in the enlarged subdural  
30 space. The aforementioned treatment techniques do not actively contribute to re-expansion of the brain within the dura, and



therefore do little to prevent the re-accumulation of fluid in the enlarged subdural space.

The subdural evacuating port system according to the present invention substantially departs from the conventional concepts and designs and methods of the prior art, and in so doing provides an apparatus and method primarily developed for the purpose of removing subdural fluid accumulations in a manner that is minimally invasive and promotes decompression, expansion, and recovery of the brain.

### **SUMMARY OF THE INVENTION**

In view of the foregoing disadvantages inherent in the known techniques and systems for removing fluids from the subdural region of a patient now present in the prior art, the present invention provides a new subdural evacuating port system with a device and method of use wherein the same can be utilized for removing subdural fluid accumulations in a manner that is minimally invasive and promotes the decompression, expansion, and recovery of the brain.

The invention includes a procedure for treating substantially liquid subdural fluid collections in a manner that is minimally invasive and does not involve touching the brain. Significantly, the procedure of the invention promotes brain expansion within the dura by creating a homogeneous, negative pressure throughout the subdural space from which the fluid collection has been removed.

The invention is especially effective when used on patients having a subdural space filled with fluid that is substantially liquid without significant coagulation of the fluid, including acute

patients that are taking anticoagulants to enhance the fluidity of the matter that has accumulated in the subdural space.

The present invention generally comprises a subdural  
5 evacuating port device including a tubular portion for partial  
insertion into an opening in a skull of a patient. The tubular  
portion has a proximal end and a distal end and a lumen extending  
between the proximal and distal ends. The port device has a pair of  
wings for facilitating finger rotation of the tubular portion, with  
10 the wings extending outwardly from the tubular portion in  
substantially opposite directions from the tubular portion. The  
exterior surface of the tubular portion may have self-tapping  
threads at the proximal end and may have a plurality of annular  
barbs at the distal end. A kit for evacuating a collection of fluid  
15 from a subdural space may include the subdural evacuating port  
device and a retractor for spacing sides of an incision in a scalp  
away from each other. The kit may include a drill bit and a stop  
collar selectively lockable in a position on the drill bit. A method  
of evacuating a fluid collection from a subdural space includes  
20 penetrating the skull to form an opening in the skull, providing the  
subdural evacuating port device, introducing the proximal end of  
the subdural evacuating port device into the opening, and creating a  
substantially uniform negative pressure condition in the subdural  
space of the patient through the subdural evacuating port device.

25 There has thus been outlined, rather broadly, the more  
important features of the invention in order that the detailed  
description thereof that follows may be better understood, and in  
order that the present contribution to the art may be better  
30 appreciated. There are additional features of the invention that

will be described hereinafter and which will form the subject matter of the claims appended hereto.

In this respect, before explaining at least one embodiment of the invention in detail, it is to be understood that the invention is not limited in its application to the details of construction and to the arrangements of the components set forth in the following description or illustrated in the drawings. The invention is capable of other embodiments and of being practiced and carried out in various ways. Also, it is to be understood that the phraseology and terminology employed herein are for the purpose of description and should not be regarded as limiting.

As such, those skilled in the art will appreciate that the conception, upon which this disclosure is based, may readily be utilized as a basis for the designing of other structures, methods and systems for carrying out the several purposes of the present invention. It is important, therefore, that the claims be regarded as including such equivalent constructions insofar as they do not depart from the spirit and scope of the present invention.

For a better understanding of the invention, its operating advantages and the specific objects attained by its uses, reference should be made to the accompanying drawings and descriptive matter in which there are illustrated preferred embodiments of the invention.

## **BRIEF DESCRIPTION OF THE DRAWINGS**

The invention will be better understood and objects other than those set forth above will become apparent when consideration is

given to the following detailed description thereof. Such description makes reference to the annexed drawings wherein:

Figure 1 is a schematic perspective view of a new subdural  
5 evacuating port device of the system of the present invention.

Figure 2 is a schematic side view of a drill and bit useful in the techniques of the present invention.

10 Figure 3 is a schematic side view of a bulb useful in the techniques of the present invention.

Figure 4 is a schematic end view of the subdural evacuating port device of the present invention.

15 Figure 5 is a schematic sectional view of subdural evacuating port device of the present invention.

20 Figure 6 is a schematic side view of a retractor useful in the techniques of the present invention.

Figure 7 is a schematic sectional view of a portion of a patient's skull and brain area with the subdural evacuating port device mounted on the skull.

## 25 **DESCRIPTION OF THE PREFERRED EMBODIMENT**

With reference now to the drawings, and in particular to Figures 1 through 7 thereof, a new subdural evacuating port system  
30 embodying the principles and concepts of the present invention will be described.

As best illustrated in Figures 1 through 7, the system of the invention generally includes a subdural evacuating port device 10,

and contemplates a kit for evacuating a collection of fluid from a subdural space of a patient that incorporates the subdural evacuating port device. The system also contemplates a method for utilizing the subdural evacuating port device and elements of the kit for removing fluid from the subdural space while facilitating the recovery of the patient's brain.

Elements useful in practicing the invention include the subdural evacuating port device 10, a drill device 12, a drill bit 14 for mounting on the drill device, a stop collar 16 for mounting on the drill bit, a retractor device 18, a negative pressure source 20, and a conduit 22.

The drill device 12 is provided for rotating the drill bit 14. The drill bit is mountable on the drill device in a suitable manner, such as by an adjustable chuck assembly 13. The chuck assembly 13 of the drill device 12 is most preferably rotated by manual means (e.g., turned by the surgeon's hand), but optionally the chuck assembly may be driven by motorized means.

The drill bit 14 is adapted for removably mounting on the drill device 12, and the drill bit 14 is preferably sized for creating a opening of a suitable size in the skull of the patient, as will be discussed in greater detail below. Illustratively, the drill bit 14 is formed of a stainless steel material.

The stop collar 16 is preferably provided for selectively limiting the maximum penetration of the tip of the drill bit 14 into the skull of the patient. The stop collar 16 is most preferably selectively lockable in a variety of longitudinal positions along the length of the drill bit 14 depending upon the depth of penetration needed to produce an opening through the skull without injuring the

brain. The stop collar 16 is provided with a channel for receiving a portion of the drill bit 14, and the stop collar has a set screw 17 for extending into the channel and abutting against the drill bit 14 for locking the stop collar in a selected longitudinal position.

- 5 Illustratively, one suitable material for the stop is a nylon, such as DELRIN.

The retractor device 18 is provided for holding back the edges of an incision made through the scalp of the patient. The retractor  
10 device 18 is especially useful for reducing the possibility of contact between the drill bit and the scalp when the drill bit is inserted through the incision for boring into the skull, and thus reduces any damage resulting from such contact. Preferably, the retraction device is of the type known as an "Holzheimer" retractor (see  
15 Figure 6). The "Holzheimer" retractor generally has two arms 56, 58 that are joined together at proximal ends of the arms to form an apex 60. The arms 56, 58 extend away from the apex 60 and terminate at free ends 62, 64 of the arms. Preferably, the free ends of the arms are spaced such that the arms form a substantially V-  
20 shaped structure. A locking member 66 may be included on the retractor for selectively locking the arms at a desired spacing. The "Holzheimer" retractor 18 has a lower edge 68 for inserting into the incision. A tab 70, 72 may be provided on each of the arms 56, 58 adjacent to the lower edge 68 at a location separated from the apex  
25 60 of the clip. The tabs 70, 72 preferably lodge themselves below the outer surface of the scalp to help hold the clip in place with respect to the incision during the period when the incision needs to be held open. Optionally, but less preferably, retraction of the scalp may be performed by other known types of surgical retractors,  
30 such as, for example, a "Mastoid" retractor, a "Gelpi" retractor, or a "Heiss" retractor.

004080" E4E3E3E0

The negative pressure device 20 is provided for creating a uniform negative pressure condition in the subdural space of the patient. The negative pressure device exerts a suction for imparting a uniform partial vacuum in the subdural space. Importantly, the magnitude of the negative pressure condition created is relatively low for exerting a gentle suction in the subdural space. The substantial uniformity of the negative pressure is considered important for promoting the gradual re-expansion of the brain in the subdural space. The magnitude of the negative pressure exerted by a suitable negative pressure source is approximately 0.8 inch to 1 inch of mercury (Hg) with respect to atmospheric pressure. It will be appreciated that a lower level (e.g., less than 0.8 inches of mercury) of negative pressure may be used, although the effectiveness of the fluid removal will be reduced. While relatively higher levels of negative pressure may be used (such as up to approximately 1.2 inches of mercury), significantly higher levels of negative pressure can hamper the recovery of the brain and the associated tissues, by, for example, not allowing the brain to fully re-expand to its condition prior to the fluid accumulating in the subdural space. The relatively low level of negative pressure permits the negative pressure condition to be maintained in the subdural space for a relatively extended period of time for removing any further collection of fluid, as well as promoting a gradual expansion of the brain in the subdural space during the healing process.

A highly preferable negative pressure source is a device commonly referred to as a Jackson-Pratt bulb (see Figure 3). The Jackson-Pratt bulb 20 has an interior and a pair of openings 24, 26. More particularly, the bulb 20 has a primary opening 24 and a

secondary opening 26, and each opening extends between the interior and an exterior of the bulb. A check valve (not shown) is provided on the bulb 20 in communication with the primary opening 24 for resisting exit of fluid (e.g., gas or liquid) from the interior to the exterior of the bulb through the primary opening while permitting fluid flow into the interior through the primary opening. A cap 28 may be provided for selectively closing the secondary opening 26 of the bulb thus requiring any fluid entering the interior to enter through the primary opening 24.

The conduit 22 may be provided for fluidly connecting the subdural evacuating port device 10 with the negative pressure source. Preferably, the conduit 22 connects the primary opening 24 of the Jackson-Pratt bulb 20 with the subdural evacuating port device 10. The conduit 22 has first 30 and second 32 ends, and the first end 30 is removably connectable to the subdural evacuating port device 10 and the second end 32 is removably connectable to the primary opening 24 of the Jackson-Pratt bulb 20. The conduit may comprise flexible tubing of the type commonly used for draining fluids from the body, such as, for example, tubing formed from a silicone material. Illustratively, a length of tubing between approximately 2 ½ and 3 feet (approximately 75 cm and 90 cm) is suitable.

A highly significant feature of the invention is the subdural evacuating port device 10 for penetrating the skull of the patient. The port device 10 includes a substantially tubular portion 40 with a lumen 42 that extends between a proximal end 36 and a distal end 38 of the port device. An exterior surface 44 of the proximal end 36 of the tubular portion is preferably provided with self-tapping threads 46 formed thereon for cutting threads into the skull of the



patient as the proximal end is inserted into a opening 8 in the patient's skull 2 and the port device is rotated in the opening. Illustratively, a longitudinal groove 48 may extend through the self-tapping threads 46 to produce thread cutting surfaces on the exterior surface 44. An exterior surface 44 of the distal end 38 of the tubular portion 40 preferably has a plurality of annular barbs 50 formed thereon for retaining the conduit 22 on the distal end 38.

Significantly, the subdural evacuating port device 10 includes a pair of wings 52, 54 extending outwardly from the tubular portion 40 which facilitate finger rotation of the tubular portion in the opening 8 of the skull 2 during the threading of the opening by the self-tapping threads 46 of the port device. Preferably, the wings 52, 54 extend in substantially opposite directions for enhancing finger grippability of the wings. The wings 52, 54 may be mounted on the tubular portion at a location substantially medially between the proximal 36 and distal 38 ends of the tubular portion 40, between the self-tapping threads 46 and the annular barbs 50.

In one illustrative and highly preferred embodiment of the port device, the diameter of the exterior surface of the tubular portion measures approximately 6 mm. The lumen has a diameter of approximately 3.8 mm. The length of the tubular portion from the distal end to the proximal portion is approximately 45 mm. The width between the tips of the wings is approximately 23 mm, and the width of the wings is approximately 5 mm. The self-tapping threads extend approximately 10 mm from the proximal end, and the annular barbs extend approximately 15 mm from the distal end.

The method aspect of the invention permits evacuation of a collection of fluid from the subdural space within the skull 2 of a

patient. One of the initial acts of the method includes determining the region of the scalp 1 of the patient that is adjacent to the location of the collection of fluid in the subdural space.

Preferably, the region is located on the patient's scalp 1 where the collection of fluid has the greatest dimension or measurement in the subdural space of the skull. The location of the greatest dimension of the fluid collection may be determined by performing an imaging study of the head of the patient using, for example, computerized tomography or magnetic resonance imaging to determine the extent of the collection of fluid. Once the greatest dimension of the collection of fluid is determined, the location of the opening to be made through the skull to the subdural cavity is selected on the scalp at a substantially central location corresponding to the greatest dimension of the collection of fluid.

The scalp 1 of the patient may be infiltrated with an anesthetic such as by injecting the anesthetic into the scalp in the region where the subdural collection of fluid has the greatest dimension. Illustratively, the anesthetic may be lidocaine or epinephrine, or other suitable anesthetic.

An incision 6 is created in the scalp 1 to expose the bone of the skull 2 of the patient. The incision 6 extends through the scalp 1, the subcutaneous tissue, the galea, and the periosteum. The retractor device 18 is introduced into the incision 6 for holding the scalp 1 adjacent to the incision away from the operating area.

An opening 8 is created in the skull 2 of the patient using the drill bit 14 mounted in the drill device 12. Preferably, the size of the opening 8 formed in the skull may be approximately 3 to 8 mm in diameter. Most preferably, the opening 8 in the skull is

approximately 5 to 7 mm in diameter. Ideally, the appropriate size opening is approximately 6 mm in diameter. The size of the drill bit 14 is such that it will create a suitable size opening in the skull.

5           The dura 3 may then be penetrated by incising the dura of the patient using, for example, a unipolar cautery device. The underlying membranes may be transected with the unipolar cautery device.

10           Fluid that has collected in the subdural space is removed from the space through the incision in the dura 3. This removal is most preferably performed through the use of the subdural evacuating port device 10. The proximal end 36 of the subdural evacuating  
15           port device 10 is introduced into the opening 8 in the skull 2. The port device 10 is rotated in the opening 8 such that the self-tapping threads 46 engage the sides of the opening and pull the proximal end 36 into the opening and secure the port device against  
20           unintentional withdrawal of the device from the opening. The dura 3 may be penetrated by the proximal end 36 of the port device 10 for placing the lumen 42 in fluid communication with the subdural area, and any collection of fluid in a subdural space.

          A substantially uniform negative pressure condition is created in the subdural space. This negative pressure condition is most  
25           preferably created through the lumen 42 of the subdural evacuating port device 10 of the invention. The first end 30 of the conduit 22 is connected to the distal end 38 of the subdural evacuating port device, with the annular barbs 50 retaining the conduit on the port device. The second end 32 of the conduit 22 is connected to the  
30           negative pressure source. The primary opening 24 of a Jackson-Pratt bulb 20 is connected to the second end 32 of the conduit 22.

To produce the negative pressure condition in the conduit 22 and the lumen 42 of the port device 10, the Jackson-Pratt bulb 20 is compressed (such as by hand gripping of the bulb) with the cap 28 removed from the secondary opening 26 to expel as much air from the bulb as possible. The cap 28 is then placed over the secondary opening 26, and the expansion of the resilient bulb from the collapsed condition produces a negative pressure condition in the interior of the bulb as well as the conduit 22 and the lumen 42 of the port device 10.

The negative pressure condition created in the lumen 42 of the port device 10 tends to draw fluid collected in the subdural space through the lumen and into the conduit 22 and into the interior of the bulb. The fluid collected in the interior of the bulb may be periodically emptied from the bulb, and the negative pressure condition may be reapplied to the subdural space through the port device using the bulb.

The negative pressure condition may be removed when drainage from the subdural space is no longer observed, or the desired re-expansion of the brain in the subdural space has occurred, or as is determined to be medically advisable. To remove the subdural evacuating port device 10, the device is rotated (e.g., using the wings 52, 54) such that the threads 46 move the port device out of the opening 8.

With respect to the above description then, it is to be realized that the optimum dimensional relationships for the parts of the invention, to include variations in size, materials, shape, form, function and manner of operation, assembly and use, are deemed readily apparent and obvious to one skilled in the art, and all

equivalent relationships to those illustrated in the drawings and described in the specification are intended to be encompassed by the present invention.

5           Therefore, the foregoing is considered as illustrative only of the principles of the invention. Further, since numerous modifications and changes will readily occur to those skilled in the art, it is not desired to limit the invention to the exact construction and operation shown and described, and accordingly, all suitable  
10       modifications and equivalents may be resorted to, falling within the scope of the invention.

## CLAIMS

I claim:

1. A subdural evacuating port device for evacuating a collection of fluid from a subdural space of a patient, comprising:  
a tubular portion for partial insertion into an opening in a skull of a patient, the tubular portion having a proximal end and a distal end and a lumen extending between the proximal and distal ends, the tubular portion having an exterior surface; and  
a pair of wings for facilitating finger rotation of the tubular portion, the wings extending outwardly from the tubular portion in substantially opposite directions from the tubular portion.
2. The subdural evacuating port device of claim 1 wherein the wings are mounted on the tubular portion at a location medial between the proximal and distal ends of the tubular portion.
3. The subdural evacuating port device of claim 1 wherein the exterior surface at the proximal end of the tubular portion has self-tapping threads formed thereon adapted for cutting threads into the opening in the skull of a patient.
4. The subdural evacuating port device of claim 1 wherein the exterior surface at the distal end of the tubular portion has a plurality of annular barbs formed thereon for retaining an end of a conduit thereon.
5. The subdural evacuating port device of claim 1 wherein the wings are mounted on the tubular portion at a location medial between the proximal and distal ends of the tubular portion,

wherein the exterior surface at the proximal end of the tubular portion has self-tapping threads formed thereon adapted for cutting threads into an opening in a skull of a patient, and wherein the exterior surface at the distal end of the tubular portion has a plurality of annular barbs formed thereon for retaining an end of a conduit thereon.

6. A kit for evacuating a collection of fluid from a subdural space of a patient having a scalp, comprising:

a subdural evacuating port device having a proximal end and a distal end, the subdural evacuating port device having a tubular portion with a lumen extending between the proximal and distal ends, an exterior surface of the proximal end of the tubular portion having self-tapping threads formed thereon for cutting threads into a skull, an exterior surface of the distal end of the tubular portion having a plurality of annular barbs formed thereon for retaining a flexible hose, and a pair of wings extending outwardly from the tubular portion, the wings extending in opposite directions.

7. The kit of claim 6 additionally comprising a drill bit for forming an opening in the skull of the patient.

8. The kit of claim 7 additionally comprising a stop collar selectively lockable in a position on the drill bit for setting the maximum penetration of the drill bit into a surface.

9. The kit of claim 6 additionally comprising a conduit having first and second ends, the first end being adapted for connection to the subdural evacuating port device, the second end of the conduit being for connection to a negative pressure source.

10. The kit of claim 6 additionally comprising a retractor for spacing sides of an incision in a scalp away from each other, the retractor comprising a pair of arms each having a proximal ends joined together to form an apex, each of the arms extending away from the apex such that distal ends of the arms are spaced from each other, the arms of the retractor forming a substantially V-shaped configuration.

11. The kit of claim 6 additionally comprising a negative pressure device for creating a negative pressure condition.

12. The kit of claim 11 wherein the negative pressure device comprises a Jackson-Pratt bulb having a pair of openings, the Jackson-Pratt bulb having an interior, the bulb having a primary opening and a secondary opening between the interior and an exterior of the bulb, a check valve in communication with the primary opening for resisting exit of fluid from the interior of the bulb to the exterior of the bulb through the primary opening and permitting fluid flow into the interior through the primary opening, a cap for selectively closing the secondary opening of the Jackson-Pratt bulb.

13. A method of evacuating a collection of fluid from a subdural space within the skull of a patient, comprising the acts of:  
forming an opening in the skull;  
providing a subdural evacuating port device having a proximal end and a distal end;  
introducing the proximal end of the subdural evacuating port device into the opening in the skull and into communication with the subdural space; and  
creating a substantially uniform negative pressure condition in the



subdural space of the patient through the subdural evacuating port device.

14. The method of claim 13 additionally comprising determining the region of the scalp where the collection of fluid in the subdural space has a greatest dimension measured along the surface of the scalp.

15. The method of claim 14 wherein the act of determining includes performing an imaging study of the skull of the patient using computerized tomography imaging to determine the extent of the collection of fluid.

16. The method of claim 13 additionally comprising infiltrating the scalp of the patient with an anesthetic by injecting the anesthetic into the scalp.

17. The method of claim 13 additionally comprising creating an incision in the scalp of the patient to expose the skull of the patient.

18. The method of claim 17 additionally comprising retracting portions of the scalp adjacent to the incision away from each other.

19. The method of claim 17 additionally comprising introducing a retractor into the incision.

20. The method of claim 13 wherein the act of forming an opening includes drilling a hole in the skull.

21. The method of claim 20 wherein the act of drilling the hole includes providing a drill bit having a diameter of

approximately 6 mm.

22. The method of claim 13 additionally comprising penetrating a dura by incising the dura of the patient with a unipolar cautery.

23. The method of claim 13 wherein the act of providing the subdural evacuating port device includes forming a tubular portion of the subdural evacuating port device with a lumen extending between the proximal and distal ends, and forming a pair of wings on an exterior surface of the tubular portion of the port device, the wings extending outwardly in opposite directions from the tubular portion.

24. The method of claim 23 wherein the act of providing the subdural evacuating port device includes forming self-tapping threads on an exterior surface on the tubular portion at the proximal, and forming a plurality of annular barbs on the exterior surface on the tubular portion at the distal end.

25. The method of claim 24 additionally comprising rotating the proximal end of the subdural evacuating port device in the opening so that the self-tapping threads engage the opening.

26. The method of claim 13 additionally comprising penetrating a dura of the patient with the proximal end of the subdural evacuating port device.

27. The method of claim 13 additionally comprising connecting a first end of a conduit to the distal end of the subdural evacuating port device and connecting a second end of the conduit to a negative pressure source

28. The method of claim 13 wherein the act of creating a negative pressure condition includes providing a negative pressure source in communication with the subdural space of the patient through the subdural evacuating port device.

29. The method of claim 28 wherein the act of providing a negative pressure condition includes connecting a Jackson-Pratt bulb to the subdural evacuating port device.

30. The method of claim 29 additionally comprising compressing the Jackson-Pratt bulb and closing a secondary opening of the Jackson-Pratt bulb by placing a cap on the secondary opening.

31. The method of claim 29 additionally comprising emptying the Jackson-Pratt bulb as fluid accumulates in the Jackson-Pratt bulb.

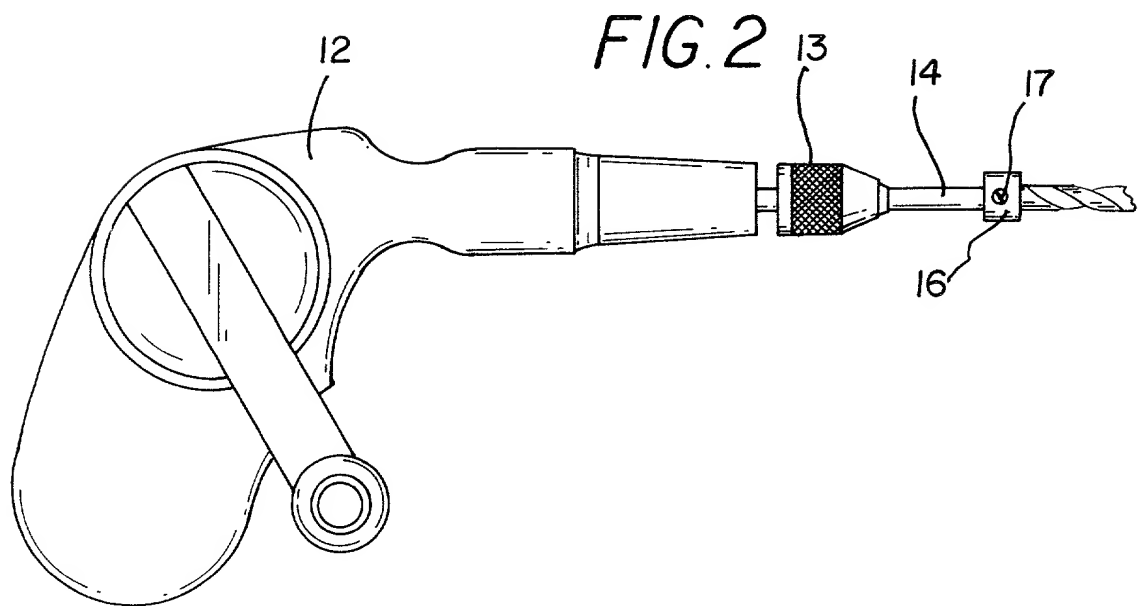
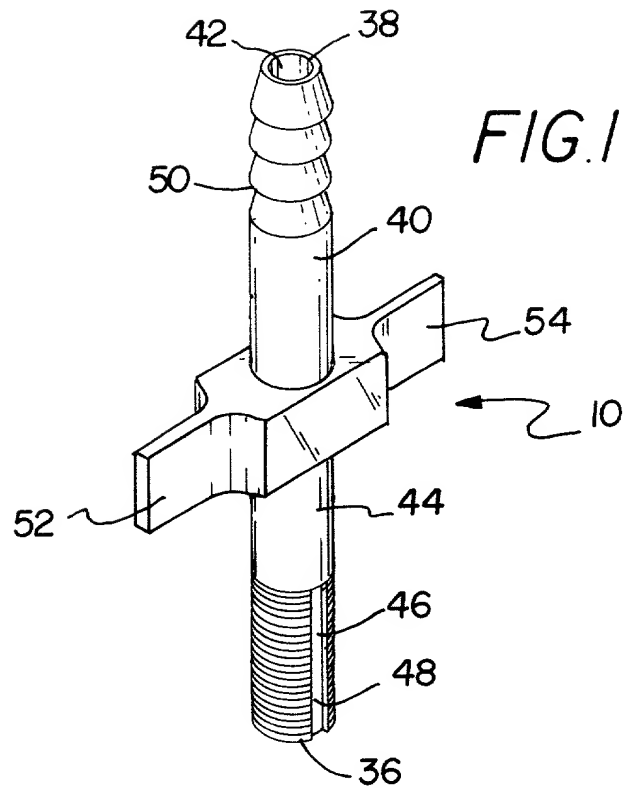
32. The method of claim 29 additionally comprising removing the negative pressure condition from the subdural space when drainage from the subdural space through the subdural evacuating port device into the Jackson Pratt bulb is no longer observed.

**ABSTRACT OF THE DISCLOSURE**

5

A subdural evacuating port system for removing subdural fluid accumulations in a manner that is minimally invasive and promotes decompression, expansion and recovery of the brain. The system includes a subdural evacuating port device including a tubular portion for partial insertion into an opening in a skull of a patient. The tubular portion has a proximal end and a distal end and a lumen extending between the proximal and distal ends. The port device has a pair of wings for facilitating finger rotation of the tubular portion, with the wings extending outwardly from the tubular portion in substantially opposite directions from the tubular portion. The exterior surface of the tubular portion may have self-tapping threads at the proximal end and may have a plurality of annular barbs at the distal end. A kit for evacuating a collection of fluid from a subdural space may include the subdural evacuating port device and a retractor for spacing sides of an incision in a scalp away from each other. The kit may include a drill bit and a stop collar selectively lockable in a position on the drill bit. A method of evacuating a fluid collection from a subdural space includes penetrating the skull to form an opening in the skull, providing the subdural evacuating port device, introducing the proximal end of the subdural evacuating port device into the opening, and creating a substantially uniform negative pressure condition in the subdural space of the patient through the subdural evacuating port device.

30



004030" E/9EE960

FIG.3

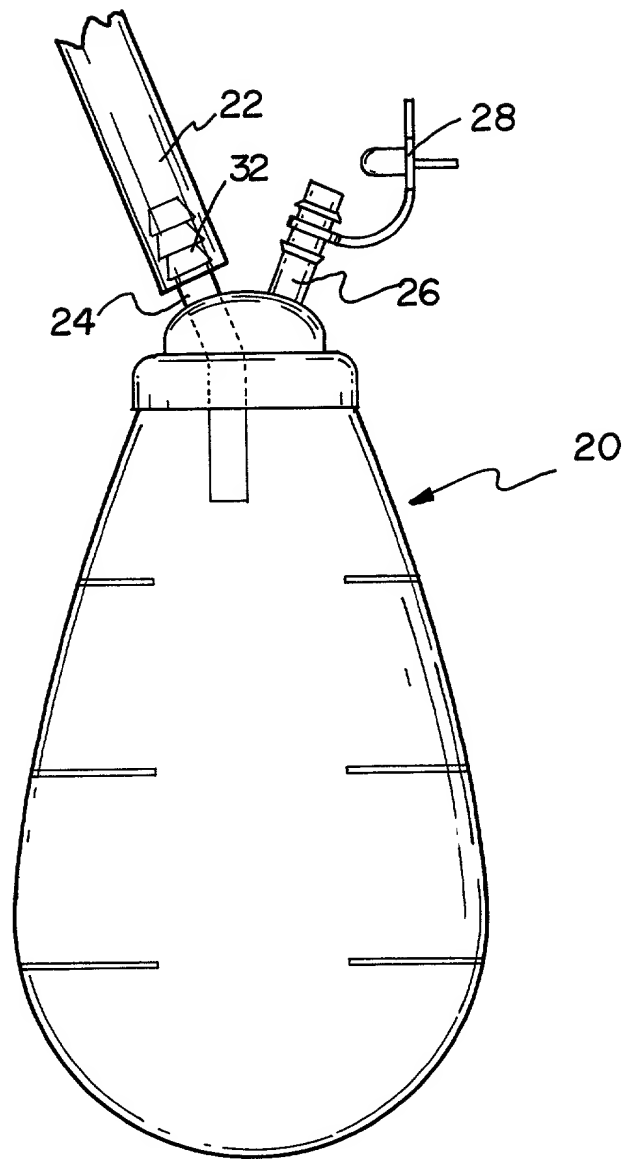
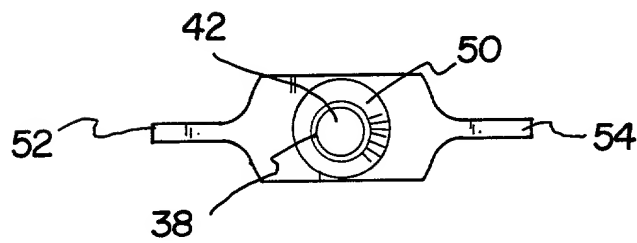
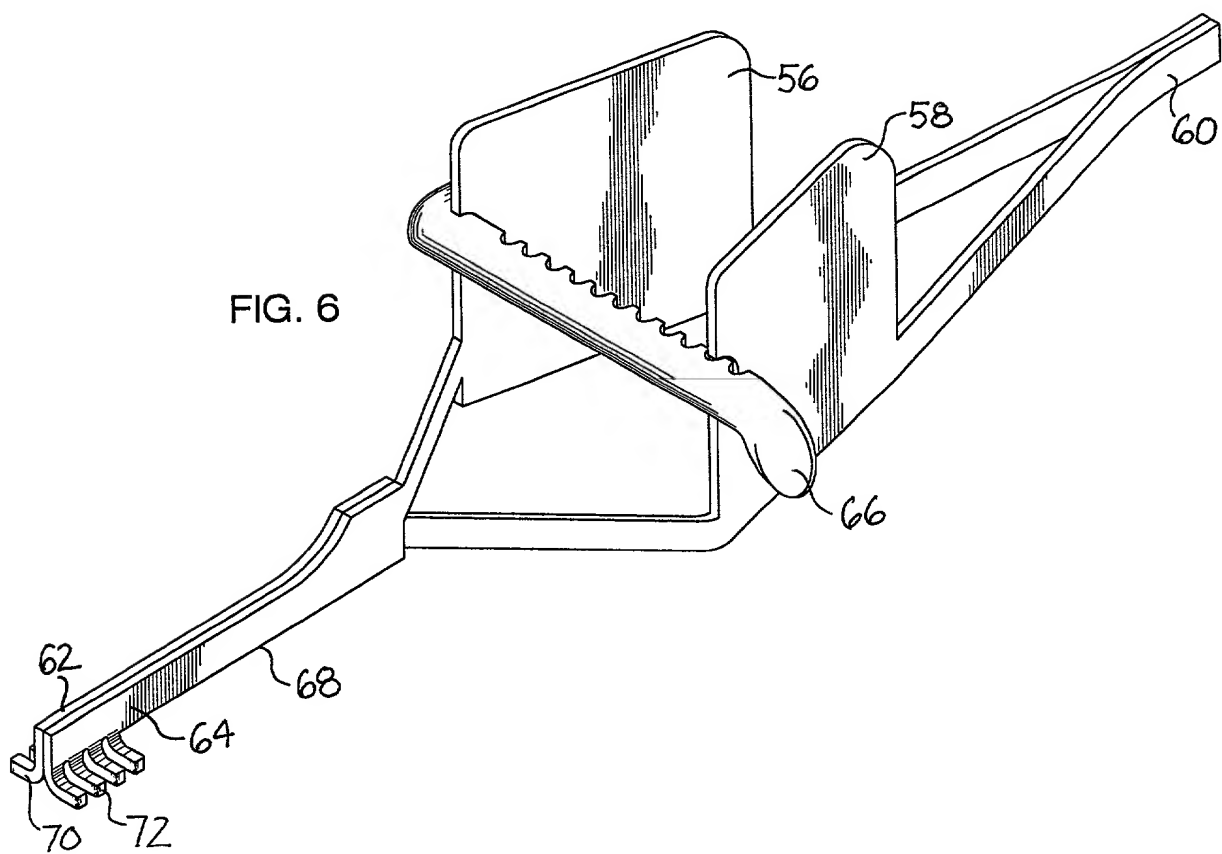
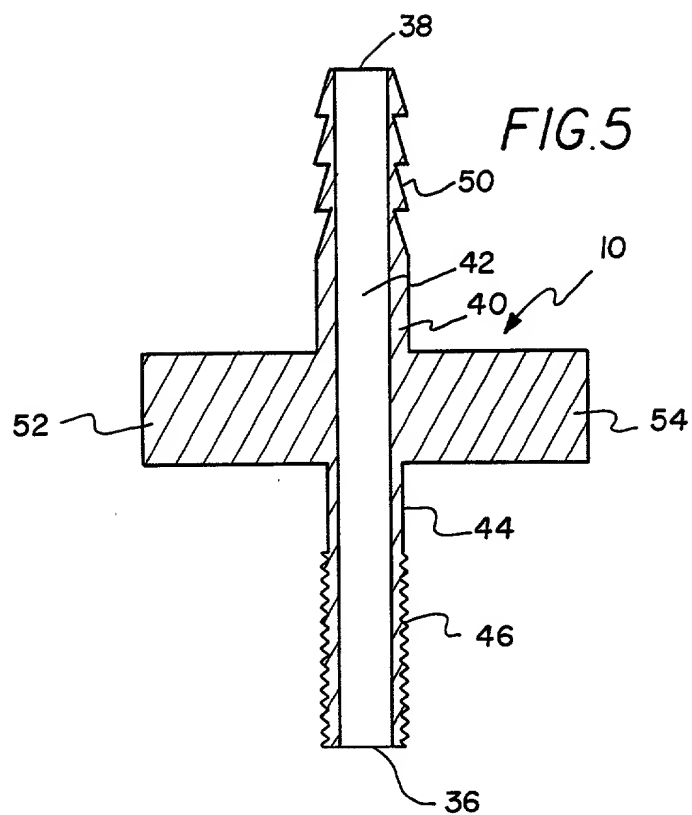
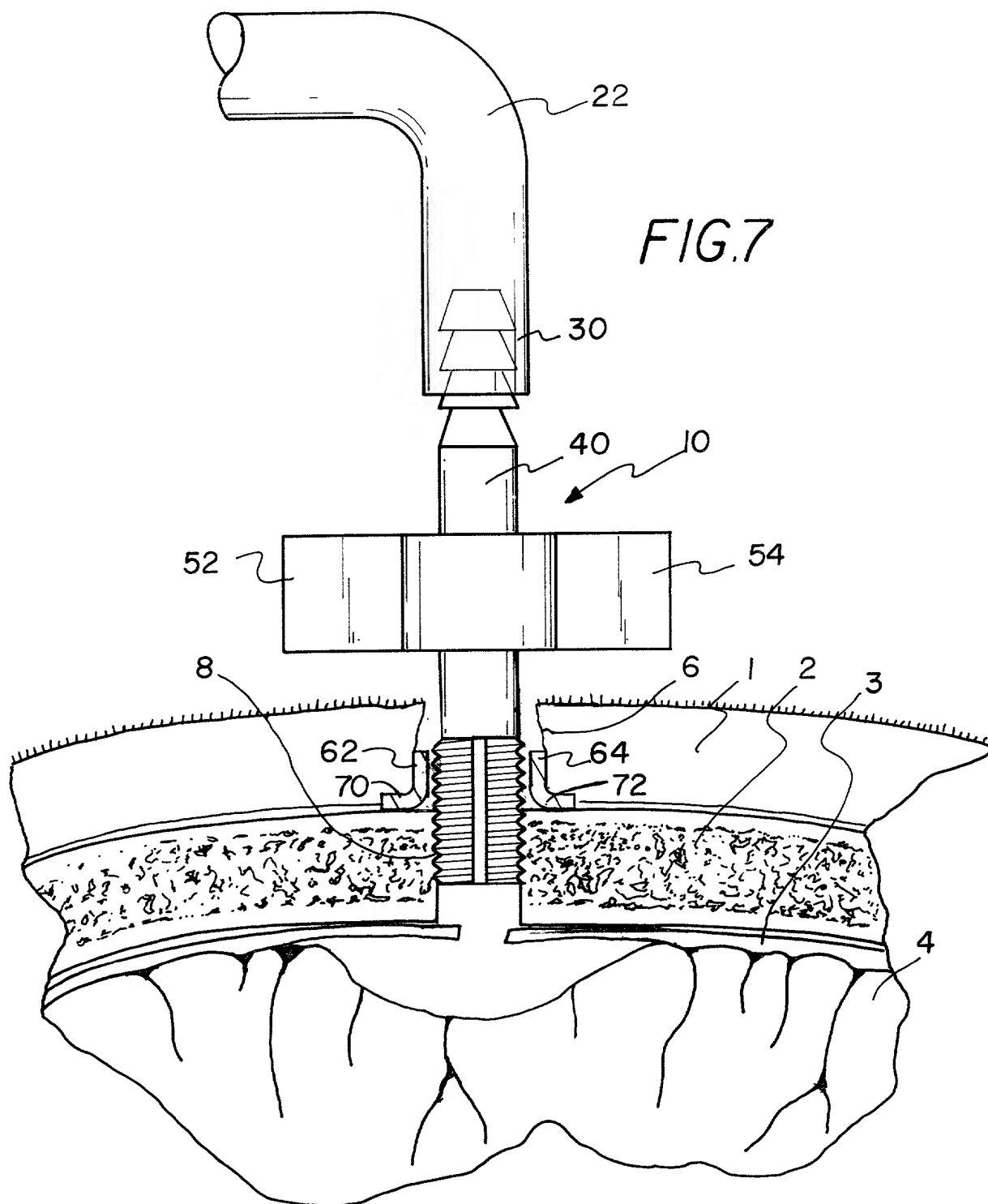


FIG.4









## **DECLARATION AND POWER OF ATTORNEY**

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

### **SUBDURAL EVACUATING PORT SYSTEM**

the specification of which is attached hereto.

I further state that I do not know and do not believe that the above-named invention has ever been known or used in the United States before my invention thereof, or patented or described in any printed publication in any country before my invention thereof, or in public use or on sale in the United States more than one year prior to this application; that the invention has not been patented or made the subject of any inventor's certificate in any country foreign to the United States on any application filed by me or my legal representatives or assigns more than one (1) year prior to this application; and that no application for patent or inventor's certificate on the invention has been filed by me or my representatives or assigns in any country foreign to the United States, except as identified below.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment if applicable.

I acknowledge the duty to disclose information to the Patent and Trademark Office all information known to me to be material to the examination of this application in accordance with Title 37, Code of Federal Regulations, Section 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(d) or Section 365(b) of any foreign application(s) for patent or inventor's certificate, or Section 365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below any foreign application for patent or inventor's certificate or PCT International application having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)

Priority Claimed

NONE  
(Number)

                      
(Country)

                      
(Day/Month/  
Year Filed)

                      
(Yes)

                      
(No)

I hereby claim the benefit under 35 U.S.C. Section 119(e) of any United States Provisional application(s) listed below:

NONE  
(Application No.)

                      
(Filing Date)

I hereby claim the benefit under Title 35, United States Code, Section 120 of any United States application(s), or Section 365 (c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of Title 35, United States Code, Section 112. I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

29/105,951  
(Application No.)

06/04/99  
(Filing Date)


pending  
(Status - patented,  
pending, abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorneys to prosecute this application and transact all business in the U.S. Patent and Trademark Office connected therewith: Ivar M. Kaardal, Registration Number 29,812.

Send Correspondence to: Kaardal & Associates, PC  
Attn: Ivar M. Kaardal  
3500 South First Ave. Circle - Suite 250  
Sioux Falls, South Dakota 57105-5807  
Telephone (605) 336-9446, FAX (605) 336-1931  
e-mail: patent@kaardal.com

Full Name of Inventor: **WILSON T. ASFORA**

  
Inventor's Signature

Date: 8-1-00

Residence: **SIOUX FALLS, SOUTH DAKOTA**

Citizenship: **UNITED STATES**

Post Office Address: **1500 WEST 22ND STREET SUITE 101  
SIOUX FALLS, SD  
57105**